MAR 2 9 2006

K053626

NEURO RESOURCE GROUP

510(k) Summary

Submitter Information:

Contact:

Krista Oakes
Tel: 972-665-1810
Fax: 972-665-1814

Date Prepared:

December 19, 2005

Product Name & Classification:

Classification Regulation: 882.1320
Panel: Neurology, Physical Medicine
Product Code: GXY
Trade Name(s): InterX 500 Flexible Array Electrode

Predicate Device:

K042912-InterX 5000

Description:

The InterX500 Flexible Array Electrode consists of stainless steel electrodes assembled in a biomedical grade silicone rubber. The electrodes are connected to each other by wiring through a connector cable. There is no power to the InterX500 Flexible Array Electrode unless it is connected to interactive electrostimulation device provided by Neuro Resource Group, Inc. The InterX500 Flexible Array Electrode is placed directly onto unbroken skin and does not use any conductive gels.

The connector is medically recognized and cannot be plugged into an AC socket. The InterX500 Flexible Array Electrode is an optional external electrode accessory for an interactive electrostimulation device provided by Neuro Resource Group. The electrode serves as an extension to the device to allow the user to apply treatment in larger and less accessible areas by the electrodes on the interactive electrostimulation device. The InterX500 Flexible Array Electrode is intended to be used with a Neuro Resource Group, Inc. provided electrostimulation device and does not contain any active electrical components. The cable is a two conductor cable using two 24 AWG single wires tinned with copper. The cable is UL and CSA approved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 2006

Neuro Resource Group
c/o Ms. Krista Oakes
Vice President, Regulatory Affairs
1100 Jupiter Road – Suite 190
Plano, Texas 75074

Re: K053626
Trade/Device Name: InterX500 Flexible Array Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GXY
Dated: March 9, 2006
Received: March 15, 2006

Dear Ms. Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) # (if known): K053626

Device Name: InterX500 Flexible Array Electrode

Indications for Use:

The InterX500 Flexible Array Electrode is intended to be used with authorized InterX TENS and/or Powered Muscle Stimulator devices for the purpose of applying electrical stimulation.

Prescription Use __x____ (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053626